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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,009	08/06/2002	Carolyn K. Goldman	NIH-05111	5287

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,009	GOLDMAN ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *6-8 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 9-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/9/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's election with traverse of Group I invention, claims 1-5 and 9-15, filed on 16 March 2004 is acknowledged. The traversal is on the ground(s) that Groups I-III, drawn to the IL-2R associated polypeptide, the antibodies produced by the hybridoma PTA-82, and a method for detecting IL-2R associated polypeptide using an antibody, have quite similar subject matter directed to related antigens and antibodies, and overlap to such an extent that there will be no serious burden on the examiner to search and examine all of the claims of groups I-III, and that groups IV-VI are related to group II, and thus, they should be examined together, and at the same time as searching and examining the claims of groups I-III. This is not found persuasive because although there is certain extent of overlap among some of the groups, any search of the prior art in regard to one group will not necessarily reveal information related to the other groups. For example, a search of the polypeptide of group I would not necessarily reveal information about the antibody of group II as they are physically and functionally distinct chemical entities, and said antibody was not even generated by using the polypeptide of group I. Additionally, a search is aimed to find references, which would render the invention obvious, as well as references directed to anticipation of the invention. Therefore, a search for one group is not adequate as to revealing references anticipating the other groups. Thus, an independent and separate searche of relevant literature in different areas of subject matter is required for each of the different groups, which constitutes undue burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Currently, claims 1-21 are pending, and claims 1-5 and 9-15 are under consideration. Claims 6-8 and 16-18 are withdrawn from further consideration as being drawn to a non-elected invention.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 9-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for the following reasons: instead of defining the polypeptide by its structural (sequence), physical or chemical features, or the source of isolation, the claim defines the polypeptide by its reactivity to a monoclonal antibody, which is an anti-idiotypic antibody to IL-2, and the association to IL-2R. Such is not sufficient to set forth the invention because a monoclonal antibody merely recognizes an epitope of a molecule, which may exist in a different molecule sharing the same epitope. As such, the claim does not clearly set forth the metes and bounds of the molecule of "an interleukin-2 receptor associated polypeptide". Further, the claim recites "a composition", which usually comprises more than one component. However, only one component is indicated in the claim, "an IL-2R association peptide". Furthermore, the claim recites "IL-2R *association peptide*" in line 2, however, there is insufficient antecedent basis for this limitation in the claim. The term "IL-2R *associated polypeptide*" is used in line 1, it is unclear whether they are used to indicate the same or different chemical entities. Furthermore, it is unclear what the term "reactive" is intended, whether it is intended to indicate binding or something else, and the specification does not define the term. The metes and bounds of the claim, therefore, cannot be determined.

Claims 2-5 and 15 are similarly indefinite for the recitation of "a composition".

Claim 2 is further indefinite because the claim recites a molecular weight, but does not specify how it is determined. It is well known in the art that molecular weight of the same molecule varies when determined by different methods. As such, the metes and bounds of the claim cannot be determined.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: certain method steps of the process. The claim merely recites one step of forming an antibody-antigen complex, which is not complete, nor sufficient to allow the achievement of the goal of purifying the polypeptide set forth in the preamble. The claim is further indefinite for the recitation of "IL-2R associated *protein*" in line 3, as it is unclear whether it is the same as "an IL-2R associated *polypeptide*" recited in line 1, and what is

being purified. The claim is further indefinite because it is unclear what antibody is being used in the method.

Claims 10 and 11 are similarly indefinite for being incomplete for omitting essential elements.

Claim 10 is further indefinite for the recitation of "wherein said cells ... are solubilized *prior to said contacting of said cells* with said antibody" because it is impossible to contact said *cells* after solubilization, as said "cells" would not exist anymore.

Claim 12 recites the limitation "said anti-ILRAP antibody" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 is indefinite because it is unclear what "interleukin β subunits" is meant, and why such cells would be expected to express the peptide of interest. The claim is further indefinite for the recitation of "said cells expressing interleukin-2" in line 1 because in the independent claim 9, the recitation is "cells expressing interleukin-2 *receptor*". Thus, it is unclear whether "said cells expressing interleukin-2" in claim 13 is a new limitation.

The remaining claims are rejected for depending from an indefinite claim.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cerretti et al., EP 0 162 699 (provided by applicants), and as evidenced by Colamonici et al. (J. Immunol., 1990, 145:155-160).

Cerretti discloses an IL-2R polypeptide isolated from Hut-102 cells, and a method for purifying the polypeptide by using an antibody to IL-2R, wherein the method involves solubilization of the cells, contacting with said antibody allowing the formation of the complex of the IL-2R and the antibody, utilizing immunoaffiity chromatography, and eluting the IL-2R protein (Examples 1 and 5). Cerretti does not specifically mention that Hut-102 cells express IL-2R. However, as evidenced by Colamonici that Hut-102 cells express IL-2R α and β subunits (page 156, the left column, and Figure 1B). As such, Cerretti's IL-2R would meet the definition of "an IL-2R associated polypeptide" in the present specification (page 8, lines 24-26), and read on the IL-2R associated polypeptide of the present invention, and therefore, claims 1 and 4 would be anticipated by, or obvious over the Cerretti reference. The reference does not specifically mention that the IL-2R would react with the monoclonal antibody (5F7) produced by the hybridoma PTA-82. The burden shifts to the applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977). Further, claims 2 and 3 would be anticipated by, or obvious over the Cerretti reference for the following reasons: with respect to the molecular weight limitation in claims 2 and 3, as the claims do not specify the method of determination, and in view of the possibility that the difference in the molecular weight between the IL-2R of the prior art and the IL-2R associated polypeptide may be due to the different ways of measurement, and the burden is on the applicant to provide evidence to the contrary.

With respect to claims 9-15, Cerretti teaches the same method steps as recited in claims 9-13, and the eluted IL-2R of the reference would meet the limitation of a composition in present claims 14 and 15. The source of isolation of the polypeptide (claim 14) does not change the

nature of the polypeptide itself. Thus, the claims would be anticipated by, or obvious over the Cerretti reference. Again, for the same reasons above, the burden shifts to the applicant to provide *evidence* that the IL-2R of the prior art is a distinct chemical entity from that of the present invention and would not react with mAb 5F7 by PTA-82, and therefore, the prior art would neither anticipate nor render obvious the claimed invention.

Claims 1-5, 9, 10, 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Colamonici et al. (J. Immunol., 1990, 145:155-160).

The teachings of Colamonici are reviewed above. Additionally, Colamonici teaches two other bands in the gel with molecular weight of 37 and 20 kDa, which co-immunoprecipitated with the IL-2R, and indicates that these bands might correspond to 2 or even 3 novel proteins very closely associated with p55 (a subunit of IL-2R) in Hut-102 cells (page 159, the last paragraph). The molecular weight of these two bands is very close to that in the present claims 2 and 3. Thus, claims 1-5 would be anticipated by, or obvious over the Cerretti reference for the same reasons above, then the burden shifts to the applicant to provide *evidence* that the prior art would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977).

With respect to claims 9, 10 and 13, Colamonici teaches the steps in those claims, i.e., solubilizing Hut-102 cells expressing IL-2R α and β subunits, contacting with an anti-IL-2R antibody to allow the formation of the complex. With respect to claims 14 and 15, Colamonici teaches a band of IL-2R polypeptide in a gel, which would meets the limitation of "a composition" in the claims. Again, the source of isolation of the polypeptide (claim 14) does not change the nature of the polypeptide itself. Therefore, claims 9, 10, and 13-15 would also be anticipated by, or obvious over the Colamonici reference for the same reasons above. The burden shifts to the applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
5/18/04